osteo symbionics™

K133082

MAY 2 0 2014

510(k) Summary of Safety and Effectiveness
(as required by 21 CFR § 807.92)

510(k) Submitter	OsteoSymbionics, LLC 1768 East 25th St STE 316 Cleveland, OH 44114
Contact Person	Nicholas Wilkins, QA/RA Manager *Phone:* (216) 881-8500 *e-mail:* nw@osteosymbionics.com
Date Prepared	December 4, 2013
Device Name	*Proprietary Name:* OsteoSymbionics Patient-Specific Cranial Implant *Common Name:* Patient-Specific Cranial Implant *Classification Name:* "Plate, cranioplasty, preformed, non-alterable," a class II device in accordance with 21 CFR § 882.5330
Device Description	The OsteoSymbionics Patient Specific Cranial Implants are individually sized and shaped implantable prosthetic cranioplasty plates intended to fill cranial defects in a specific patient. The implants are composed of polymethyl methacrylate and are fabricated using the patient's CT imaging data. The devices are provided sterile and are attached to the native bone with commercially available cranioplasty fasteners.
Indication for Use	The OsteoSymbionics Patient-Specific Cranial Implants are designed individually for each patient to correct cranial defects.
Substantial Equivalence	The OsteoSymbionics Patient-Specific Cranial Implants are substantially equivalent in terms of safety and effectiveness to the following legally marketed device: OsteoSymbionics Patient-Specific Cranial Implants (K072601) These devices are identical except for the modification that they will be packaged and supplied sterile, instead of being supplied non-sterile with instructions for sterilization.
Summary of Testing	Safety and effectiveness of the sterilized OsteoSymbionics Patient -Specific Cranial Implant has been established through comparative analysis of physical properties and biocompatibility through standardized testing. Physical properties are comparable to the legally marketed device, and biocompatibility is unaffected by the change in sterilization. The sterilization and packaging validations will confirm that a sterility level of 10-6 is achieved.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 20, 2014

OsteoSymbionics, LLC
Mr. Nicholas Wilkins
QA/RA Manager
1768 East 25th St., STE 316
Cleveland, OH 44114

Re: K133082
Trade/Device Name: OsteoSymbionics Patient-Specific Cranial Plate
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed non-alterable cranioplasty plate
Regulatory Class: Class II
Product Code: GXN
Dated: March 31, 2014
Received: April 2, 2014

Dear Mr. Wilkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133082

Device Name
OsteoSymbionics Patient-Specific Cranial Implant

Indications for Use *(Describe)*

The OsteoSymbionics Patient-Specific Cranial Implants are designed individually for each patient to correct cranial defects.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."